

4. Janssen Ad26.COV2.S (COVID-19) Vaccine

4.1 Vaccine Composition, Dosing Regimen

The Janssen Ad26.COV2.S vaccine is a colorless to slightly yellow, clear to very opalescent sterile suspension for intramuscular injection. The vaccine consists of a replication-incompetent recombinant adenovirus type 26 (Ad26) vector expressing the severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2) spike (S) protein in a stabilized conformation. The vaccine also contains the following inactive ingredients: citric acid monohydrate, trisodium citrate dihydrate, ethanol, 2-hydroxypropyl- β -cyclodextrin (HBCD), polysorbate 80, sodium chloride, sodium hydroxide, and hydrochloric acid.

The Ad26 vector expressing the SARS-CoV-2 S protein is grown in PER.C6® TetR Cell Line, in media containing amino acids and no animal-derived proteins. After propagation, the vaccine is processed through several purification steps, formulated with inactive ingredients and filled into vials.

The Ad26.COV2.S vaccine is provided as a refrigerated suspension [stored at 2°C to 8°C (36°F to 46°F)] in a multi-dose vial containing 5 doses (0.5 mL each). The vials should be protected from light. Unpunctured vials may be stored between 9°C to 25°C (47°F to 77°F) for up to 12 hours. After the first dose has been withdrawn, the vial should be held between 2° to 8°C (36° to 46°F) for up to 6 hours or at room temperature (maximally 25°C/77°F) for up to 2 hours. The vial should be discarded if the vaccine is not used within these times.

Ad26.COV2.S (5×10^{10} vp) is administered as a single intramuscular injection (0.5 mL dose).

FDA has reviewed the CMC data submitted to date for this vaccine and has determined that the CMC information is consistent with the recommendations set forth in FDA's guidance [Emergency Use Authorization for Vaccines to Prevent COVID-19](#) (October 2020). As such, FDA